Iveric Bio Announces Fast Track Designation from U.S. FDA for Zimura® for the Treatment of Geographic Atrophy Secondary to Dry Age-Related Macular Degeneration

April 3, 2020

NEW YORK--(BUSINESS WIRE)--Apr. 3, 2020-- IVERIC bio, Inc. (Nasdaq: ISEE) announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to Zimura® (avacincaptad pegol), a novel complement C5 inhibitor, in development for the treatment of geographic atrophy (GA) secondary to dry age-related macular degeneration (AMD). The FDA created the Fast Track process to facilitate the development and expedite the review of drugs to treat serious or life-threatening diseases or conditions, which have the potential to fill an unmet medical need. Fast Track designation offers important benefits, including frequent interactions with the FDA and the potential eligibility for Rolling Submission and Priority Review of a New Drug Application, if relevant criteria are met. Currently, there is no FDA or EMA approved treatment option available for patients with GA secondary to dry AMD.

"With no treatment options available for patients with geographic atrophy secondary to dry age-related macular degeneration the FDA's Fast Track designation recognizes the potential of Zimura to address this unmet medical need," stated Glenn P. Sblendorio, Chief Executive Officer and President of IVERIC bio. "Should the positive results from our initial Zimura pivotal clinical trial be confirmed by our second pivotal clinical trial, we believe this important designation may help expedite the registration of Zimura as a treatment option for our patients. We look forward to working closely with the FDA."

On October 28, 2019, the Company announced that Zimura met its pre-specified primary efficacy endpoint and reached statistical significance in an international, multicenter, randomized, double masked, sham controlled clinical trial in GA secondary to dry AMD, referred to as the OPH2003 trial. Zimura was generally well tolerated after 12 months of administration. IVERIC bio provided further details supporting the positive results from this pivotal trial in its Annual Report on Form 10-K filed on February 27, 2020.

Geographic Atrophy

Age-related macular degeneration (AMD) is the major cause of moderate and severe loss of central vision in aging adults, affecting both eyes in the majority of patients. The macula is a small area in the central portion of the retina responsible for central vision. As AMD progresses, the loss of retinal cells and the underlying blood vessels in the macula results in marked thinning and/or atrophy of retinal tissue. Geographic atrophy, the advanced stage of AMD, leads to further irreversible loss of vision in these patients. There are currently no U.S. Food and Drug Administration (FDA) or European Medicines Agency (EMA) approved treatment options available for patients with geographic atrophy.

Zimura

Complement factor C5 is a central component of the complement cascade and is believed to be involved in the development and progression of dry AMD. Zimura is designed to target and inhibit complement factor C5. Zimura binds to C5 and inhibits its cleavage into the terminal fragments, C5a and C5b. By inhibiting the formation of complement system terminal fragments, Zimura may decrease the activation of inflammasomes and the formation of membrane attack complex (MAC), which occur at the end of the complement cascade. This mechanism of action could potentially prevent or slow down the degeneration of retinal pigment epithelial (RPE) cells providing the potential therapeutic rationale in GA secondary to dry AMD.

About IVERIC bio

IVERIC bio is a biopharmaceutical company focused on the discovery and development of novel treatment options for retinal diseases with significant unmet medical needs. Vision is Our Mission. For more information on the Company please visit www.ivericbio.com.

Forward-looking Statements

Any statements in this press release about the Company's future expectations, plans and prospects constitute forward-looking statements for purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. Forward-looking statements include any statements about the Company's strategy, future operations and future expectations and plans and prospects for the Company, and any other statements containing the words "anticipate," "believe," "estimate," "expect," "intend", "goal," "may", "might," "plan," "predict," "project," "seek," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions. In this press release, the Company's forward looking statements include statements about the potential future benefits of Fast Track designation, its expectations to use OPH2003 trial of Zimura for the treatment of geographic atrophy as a pivotal trial, its development strategy for Zimura, the implementation of its business plan, the timing, progress and results of clinical trials and other research and development activities and the potential utility of its product candidates. Such forward-looking statements involve substantial risks and uncertainties that could cause the Company's development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, those related to the initiation and the progress of research and development programs and clinical trials, availability of data from these programs, reliance on university collaborators and other third parties, establishment of manufacturing capabilities, expectations for regulatory matters, need for additional financing and negotiation and consummation of business development transactions and other factors discussed in the "Risk Factors" section contained in the quarterly and annual reports that the Company files with the Securities and Exchange Commission. Any forward-looking statements represent the Company's views only as of the date of this press release. The Company anticipates that subsequent events and developments will cause its views to change. While the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so except as required by law.

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